From: Jarbeau, Tammy (HC/SC)
Sent: 2023-12-08 4:37 PM
To: [redacted]
Cc: Maddison, Anna (HC/SC)
Subject: Health Canada response

Good afternoon[redacted],

On behalf of my colleague Anna, please find below the responses to your latest questions.

If you could kindly acknowledge receipt, it would be appreciated.

Thank you

Tammy

—

Health Canada's independent drug authorization process is recognized around the world for its high standards and rigorous review. Health Canada continues to monitor COVID-19 vaccines to ensure that they continue to meet the highest standards for safety, effectiveness and quality and that their benefits continue to outweigh any potential risks.

We invite you to consult information available online about vaccine development and approval in Canada, which can be found here. Information about Health Canada's review and authorization of vaccines can be found here.

More information about the development of mRNA vaccines can be found here, and information specific to COVID-19 mRNA vaccines is available here.

Finally, detailed technical information about the Pfizer-BioNTech COVID-19 vaccine can be found at the links below. These include technical resources such as the product monograph, and the regulatory decision summary, which explains Health Canada's decision to grant market authorization:

- Pfizer-BioNTech Comirnaty® vaccine regulatory information
- Pfizer-BioNTech Comirnaty® Original and Omicron BA.4/BA.5, bivalent COVID-19 vaccine regulatory information
- Pfizer-BioNTech Comirnaty® Omicron XBB.1.5, monovalent COVID-19 vaccine regulatory information

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You wrote: *"The SV40 promoter enhancer sequence was found to be a residual DNA fragment in Pfizer-BioNTech COVID-19 vaccine. The fragment is inactive, has no functional role, and was measured to be consistently below the limit required by Health Canada and other international regulators."* ***What evidence do you have to say that the fragment is inactive?***

When you say it has no functional role, do you mean it has no functional role in the plasmid, or that it has no function if transfected into humans? If it has no role, then why is it there?

When you say it was measured below the limit, what is the specific limit for the SV40

enhancer-promoter? Please provide the measurements obtained and the technique(s) used.

You wrote: *"Any claims that the presence of the SV40 promoter enhancer sequence is linked to an increased risk of cancer are unfounded."* ***Can you provide your risk assessment that supports that statement? What studies have been performed to assess the risk of cancer due to the vaccine generally, and associated with this sequence?***

The limit for residual DNA in biologic drugs required by Health Canada for approval is not more than 10 ng/human dose. This is in line with the World Health Organization's recommendation concerning residual DNA in biological drugs, and consistent with the quality limits of other international regulators.

Monitoring of the residual DNA fragments is conducted by the manufacturers using methods that have been reviewed and approved by Health Canada as appropriate for its purposes. All Pfizer-BioNTech's COVID-19 vaccine commercial batches released in Canada complied with the requirements approved by Health Canada, including the residual DNA. The plasmid used for the Pfizer vaccine production is linearized, degraded, and reduced in quantity through additional steps and the fragments are inactive and non-functional. There is no peer reviewed evidence that linearized or fragmented DNA is capable of translocating to the nucleus of cells.

You also imply that the lack of function of this SV40 sequence was the reason why it was omitted from the plasmid map disclosed by Pfizer-BioNTech. We also point out that the AmpR promoter was also omitted from the plasmid map. This cannot be said to lack function because without it the antibiotic resistance gene can't function. And without that E. coli that have incorporated plasmid cannot be selected. And without that modRNA cannot be produced. Accordingly, the justification for excluding the SV40 enhancer-promoter sequences fails. Please comment.

Why didn't Pfizer-BioNTech provide the full plasmid map annotated with functional sequences? When we enter the sequence in SnapGene (Fasta file available here: https://mega.nz/file/kMxDzCZA#zJWpWr3KsfvVeQP94UBKehFkhfVft_Pg5Oblo1Yt1N8), we can clearly see the SV40 enhancer-promoter-ori region.

Did Pfizer-BioNTech manually alter the plasmid map before providing it to Health Canada? Why did Health Canada not verify the map and instead had to learn about it from independent scientists like McKernan and Buckhaults? Also, can you please provide the software program used to produce the plasmid map disclosed by Pfizer-BioNTech? Can you name the software program you used?

You have quoted WHO guidelines with regards to residual DNA in biological drugs. WHO guidelines address a number of issues in that regard. For example, from the WHO Expert Committee on Biological Standardization: *"The complete nucleotide sequence of the plasmid DNA should be provided. In addition, the identity, source, isolation and sequence of the gene encoding the antigen(s); a description of the steps involved in the construction of the entire plasmid; a detailed functional map of the plasmid; information on the source and function of component parts of the plasmid known to have biological activities,such as origins of replication, viral/eukaryotic promoters and other expression signals and genes encoding selection markers, should be provided. A clear rationale should be provided for the use of specific regions of DNA, such as the promoter or a gene encoding a selection marker and special attention should be given to the nature of a selection marker…Any modifications to the original native sequence(s) of the antigen should be described and explained. The location of mammalian promoters in relation to antibiotic resistance genes and the use of novel promoters or inducers should be carefully considered. Certain sequences with properties of mobile elements, such as insertion sequences or retroviral-like long terminal repeats (LTRs), should be avoided. Oncogenes are not recommended*

unless justified. It is also recommended that genes encoding enzymatic activity or a biological function be either inactivated by genetic manipulation to remove any undesirable activity, or justified. Further, although the relevance at this stage may not be understood, as part of characterization, a DNA sequence homology check of the plasmid with the international databases (e.g. the National Center for Biotechnology Information, National Institute for Health, USA, and/or other international nucleotide databases) should be performed to investigate the presence of unintended sequences of biological significance such as those encoding cellular growth functions or alternative and unanticipated reading frames. The identity of the plasmid after transfection into the bacterial cell to be used for production should be confirmed in addition to the phenotype of the cell. Representative restriction enzyme maps may be useful. Rearrangements of the plasmid within the host bacterial cell are not acceptable." ***Pfizer-BioNTech did not follow some of those guidelines with regards to providing Health Canada the full plasmid map, identifying the promoter, etc. Why is that? How is that acceptable for Health Canada? How did Health Canada engage Pfizer-BioNTech after discovering the missing data?***

After discovering the SV40 sequence, has Health Canada engaged with Pfizer-BioNTech about other sequences which the WHO guidelines requires them to disclose, namely: SV40 poly signal and HSV-TK poly A signal (Herpes simplex virus thymidine kinase)?

Going further on the plasmid map (enclosed), can you comment on the Open Reading Frame (ORF) present in the plasmid that runs as long as the spike protein but in the opposite direction (green half-circle arrow). What is it? Should it be there? Why is it there? Was it identified by Pfizer-BioNTech? If no, how is this being addressed by Health Canada? The ORF is reportedly more closely associated with a silk protein.

Did Pfizer-BioNTech or Health Canada examine the other possibly functional ORFs present on the plasmid?

Regarding the larger issue of DNA left-over impurities/contamination from the manufacturing process, can you provide us with the drug substance testing data? We'd like to see the residual DNA content per vaccine batch and the method by which the results were obtained. We're also seeking data on the fragmentation or the intactness of the RNA.

As a regulator of vaccines, Health Canada sets quality standards and requirements for manufacturers to follow, including providing comprehensive and detailed information about the vaccine itself, and about the manufacturing process. In the manufacture of any vaccine, it is expected that there may be variabilities or residual elements that are part of the standard manufacturing process. To manage this, Health Canada requires strict quality limits and controls for the presence of these residual fragments to ensure that the vaccine continues to be safe, and that any residual fragments are both inactive and have no functional role in the vaccine.

In the case of the Pfizer-BioNTech COVID-19 vaccine, the full DNA sequence of the Pfizer plasmid was provided at the time of initial filing, though it did not specifically identify the SV40 promoter enhancer sequence. The SV40 promoter enhancer sequence was found to be a residual DNA fragment in Pfizer-BioNTech COVID-19 vaccine. The fragment is inactive, has no functional role, and was measured to be consistently below the limit required by Health Canada and other international regulators.

Monitoring of the residual DNA fragments is conducted by the manufacturers using methods that have been reviewed and validated by Health Canada as appropriate for its purposes. All Pfizer-BioNTech's COVID-19 vaccine commercial batches released in Canada complied with the requirements approved by Health Canada, including the residual DNA.
-
The manufacturer does provide proprietary information and data to Health Canada for evaluation. However, Health Canada cannot disclose manufacturers' proprietary information, which includes

the type of methods, or details of the methods, used for manufacturing and control.
Finally, in reference to a previous correspondence between us, you said that Pfizer-BioNTech's Process 1 was "not plasmid-free." What was the purpose of using that plasmid? Was the map for that plasmid provided? Did it contain the SV40 enhancer-promoter, antibiotic resistance and other sequences? Can you provide this fully annotated plasmid map? How much amplification was performed from that plasmid?

Pfizer-BioNTech's submission provided information that process 1 was used for clinical trials and process 2 was used for commercial scale ups. The residual DNA limit is the same for both processes and is in line with the recommendation from the World Health Organization. The comparability of the vaccine produced by these two processes was demonstrated based on their biological, chemical and physical characteristics.

Tammy Jarbeau
She, her / elle

Senior Media Relations Advisor | Communications and Public Affairs Branch
Serving Health Canada and the Public Health Agency of Canada | Government of Canada
tammy.jarbeau@hc-sc.gc.ca / Tel: 343-999-6334

Conseillère principale des relations avec les médias | Direction générale des affaires publiques et de communications
Au service de Santé Canada et de l'Agence de la santé publique du Canada | Gouvernement du Canada
tammy.jarbeau@hc-sc.gc.ca / Tél : 343-999-6334

From: Maddison, Anna (HC/SC)
Sent: 2023-11-09 10:42 AM
To: [redacted]
Cc: HEALTH MEDIA SANTÉ (HC/SC); [redacted]
Subject: Re: Health Canada - response

Hi [redacted],

Yes, the request was received. We are working on a response.

Thanks,
Anna

On Nov 9, 2023, at 10:35 AM, [redacted] wrote:

Hi,

We didn't get an acknowledgement of reception on this one, just want to make sure you received it.

Thank you!

[redacted]
The Epoch Times
195 Allstate Parkway
Markham, ON, L3R 1P8
P [redacted]
E [redacted]
www.TheEpochTimes.com

Begin forwarded message:

From: [redacted]
Subject: Re: Health Canada - response
Date: November 3, 2023 at 2:53:44 PM GMT-4
To: "Maddison, Anna (HC/SC)" <anna.maddison@hc-sc.gc.ca>
Cc: [redacted]

Good day,
We have follow-up questions on your response on the SV40 enhancer-promoter.
You wrote:
"The SV40 promoter enhancer sequence was found to be a residual DNA fragment in Pfizer-BioNTech COVID-19 vaccine. The fragment is inactive, has no functional role, and was measured to be consistently below the limit required by Health Canada and other international regulators."
1. What evidence do you have to say that the fragment is inactive?
2. When you say it has no functional role, do you mean it has no functional role in the plasmid, or that it has no function if transfected into humans? If it has no role, then why is it there?

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Accordingly, the justification for excluding the SV40 enhancer-promoter sequences fails. Please comment.
3. When you say it was measured below the limit, what is the specific limit for the SV40 enhancer-promoter? Please provide the measurements obtained and the technique(s) used.
You wrote:
"*Any claims that the presence of the SV40 promoter enhancer sequence is linked to an increased risk of cancer are unfounded.*"
4. Can you provide your risk assessment that supports that statement? What studies have been performed to assess the risk of cancer due to the vaccine generally, and associated with this sequence?
5. Why didn't Pfizer-BioNTech provide the full plasmid map annotated with functional sequences? When we enter the sequence in SnapGene (Fasta file available here: https://mega.nz/file/kMxDzCZA#zJWpWr3KsfvVeQP94UBKehFkhfVft_Pg5OblO1Yt1N8), we can clearly see the SV40 enhancer-promoter-ori region.
6. Did Pfizer-BioNTech manually alter the plasmid map before providing it to Health Canada? Why did Health Canada not verify the map and instead had to learn about it from independent scientists like McKernan and Buckhaults? Also, can you please provide the software program used to produce the plasmid map disclosed by Pfizer-BioNTech? Can you name the software program you used?

7. You have quoted WHO guidelines with regards to residual DNA in biological drugs. WHO guidelines address a number of issues in that regard. For example, from the WHO Expert Committee on Biological Standardization:
(Emphasis added)
"*The complete nucleotide sequence of the plasmid DNA should be provided.*
In addition, the identity, source, isolation and sequence of the gene encoding the antigen(s); a description of the steps involved in the construction of the entire plasmid;
a detailed functional map of the plasmid; information on the source and function of component parts of the plasmid known to have biological activities,
such as origins of replication, viral/eukaryotic promoters and other expression signals
and genes encoding selection markers, should be provided. A clear rationale should be provided for the use of specific regions of DNA, such as the promoter or a gene encoding a selection marker and special attention should be given to the nature of a selection marker.
"*Any modifications to the original native sequence(s) of the antigen should be described and explained. The location of mammalian promoters in relation to antibiotic resistance genes and the use of novel promoters or inducers should be carefully considered. Certain sequences with properties of mobile elements, such as insertion sequences or retroviral-like long terminal repeats (LTRs), should be avoided. Oncogenes are not recommended unless justifi ed. It is also recommended that genes encoding enzymatic activity or a biological function be either inactivated by genetic manipulation to remove any undesirable activity, or justified.*
Further, although the relevance at this stage may not be understood, as part of characterization, a DNA sequence homology check of the plasmid with the international databases
(e.g. the National Center for Biotechnology Information, National Institute for Health, USA, and/or other international nucleotide databases) should be performed to investigate the presence of unintended sequences of biological significance such as those encoding cellular growth functions or alternative and
unanticipated reading frames. The identity of the plasmid after transfection into the bacterial cell to be used for production should be confirmed in addition to the phenotype of the cell. Representative restriction enzyme maps may be useful. Rearrangements of the plasmid within the host bacterial cell are not acceptable."
Pfizer-BioNTech did not follow some of those guidelines with regards to providing Health Canada the full plasmid map, identifying the promoter, etc. Why is that? How is that acceptable for Health Canada?

How did Health Canada engage Pfizer-BioNTech after discovering the missing data?

8. After discovering the SV40 sequence, has Health Canada engaged with Pfizer-BioNTech about other sequences which the WHO guidelines requires them to disclose, namely: SV40 poly signal and HSV-TK poly A signal (Herpes simplex virus thymidine kinase)?

9. Going further on the plasmid map (enclosed), can you comment on the Open Reading Frame (ORF) present in the plasmid that runs as long as the spike protein but in the opposite direction (green half-circle arrow). What is it? Should it be there? Why is it there? Was it identified by Pfizer-BioNTech? If no, how is this being addressed by Health Canada?

The ORF is reportedly more closely associated with a silk protein.

10. Did Pfizer-BioNTech or Health Canada examine the other possibly functional ORFs present on the plasmid?

11. Regarding the larger issue of DNA left-over impurities/contamination from the manufacturing process, can you provide us with the drug substance testing data? We'd like to see the residual DNA content per vaccine batch and the method by which the results were obtained. We're also seeking data on the fragmentation or the intactness of the RNA.

12. Finally, in reference to a previous correspondence between us, you said that Pfizer-BioNTech's Process 1 was "not plasmid-free."

a. What was the purpose of using that plasmid?

b. Was the map for that plasmid provided? Did it contain the SV40 enhancer-promoter, antibiotic resistance and other sequences?

c. Can you provide this fully annotated plasmid map?

d. How much amplification was performed from that plasmid?

We greatly appreciate your expertise and engagement on this.

Thank you and best regards,

[redacted]
The Epoch Times
195 Allstate Parkway
Markham, ON, L3R 1P8
P [redacted]
E [redacted]
www.TheEpochTimes.com

On Oct 27, 2023, at 4:35 PM, Maddison, Anna (HC/SC) <anna.maddison@hc-sc.gc.ca> wrote:

Good afternoon,

Please find below Health Canada's statement in response to your request.

Thanks and have a good evening,
Anna

Health Canada initially authorized the Pfizer-BioNTech COVID-19 mRNA vaccine in December 2020 and subsequently has authorized updated versions, including the most recent vaccine targeting the XBB Omicron subvariant in September 2023. Each assessment included a determinationthat the vaccine met the Department's stringent regulatory safety, efficacy and quality requirements for use in Canada.

As a regulator, Health Canada sets quality standards and requirements for manufacturers to follow, including providing comprehensive and detailed information about the vaccine itself, and about the manufacturing process. In the manufacture of any vaccine, residual elements that are part of the standard manufacturing process may remain. There are strict limits and controls for the presence of these residual fragments to ensure that there is no effect on the safety or effectiveness of the vaccine.

The Pfizer-BioNTech COVID-19 vaccine does not contain simian virus 40 (SV40). The presence of the SV40 promoter enhancer sequence is not the same as the presence of the whole virus itself.

The SV40 promoter enhancer sequence was found to be a residual DNA fragment in Pfizer-BioNTech COVID-19 vaccine. The fragment is inactive, has no functional role, and was measured to be consistently below the limit required by Health Canada and other international regulators.

Any claims that the presence of the SV40 promoter enhancer sequence is linked to an increased risk of cancer are unfounded. There is also no evidence to

support that the presence of the full SV40 in any vaccine increases the risk of cancer or the acceleration of cancer in individuals.

Health Canada continues to monitor the COVID-19 vaccines to ensure that they continue to meet the highest standards for safety, effectiveness and quality and that their benefits continue to outweigh any potential risks.

Anna Maddison
She, her / elle
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Serving Health Canada and the Public Health Agency of Canada | Government of Canada
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- - -
Media | Média T: 613-957-2983 E/CE: media@hc-sc.gc.ca

From: [redacted]
Sent: Monday, October 23, 2023 1:45 PM
To: HEALTH MEDIA SANTÉ (HC/SC) <media@hc-sc.gc.ca>
Cc: [redacted]
Subject: Follow-up questions regarding DNA plasmids and SV40 sequence in COVID-19 vaccines

Hello,

I hope you are well.

I have a few follow-up questions with regard to our previous conversation about DNA plasmids and the SV40 sequence in the mRNA vaccines.

This pre-print paper released by Dr. Kevin McKernan on Oct. 20 found the presence of billions to hundreds of billions of DNA molecules in Pfizer COVID-19 vaccine vials, which was above the guidelines for residual DNA set by the FDA and WHO by 188 to 509-fold. It says the

plasmid is likely inside lipid nanoparticles and protected from nucleases. The vials are from Ontario.

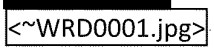
My questions are whether Health Canada was aware of this paper, what the implications of the findings could be, and if they are concerned with the findings.

We know it's not peer-reviewed, but this is nevertheless the latest science, which has helped you identify the undisclosed presence of SV40. Regarding this particular issue, has Health Canada engaged with Pfizer after discovering the undisclosed presence of the SV40 DNA sequence in the Pfizer vaccine? If yes, what was the nature of the discussions? If not, why?

Thank you.

--

[redacted]
The Epoch Times
[redacted]



From: [redacted]
Sent: 2023-11-09 10:35 AM
To: Maddison, Anna (HC/SC); HEALTH MEDIA SANTÉ (HC/SC)
Cc: [redacted]
Subject: Fwd: Health Canada - response

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Thank you.

--

[redacted] The Epoch Times

<~WRD0001.jpg>

From: [redacted]
Sent: 2023-11-03 2:54 PM
To: Maddison, Anna (HC/SC)
Cc: [redacted]
Subject: Re: Health Canada - response

Follow Up Flag: Follow up
Flag Status: Flagged

Good day,
We have follow-up questions on your response on the SV40 enhancer-promoter.
You wrote:
"The SV40 promoter enhancer sequence was found to be a residual DNA fragment in Pfizer-BioNTech COVID-19 vaccine. The fragment is inactive, has no functional role, and was measured to be consistently below the limit required by Health Canada and other international regulators."
1. What evidence do you have to say that the fragment is inactive?
2. When you say it has no functional role, do you mean it has no functional role in the plasmid, or that it has no function if transfected into humans? If it has no role, then why is it there?

You also imply that the lack of function of this SV40 sequence was the reason why it was omitted from the plasmid map disclosed by Pfizer-BioNTech. We also point out that the AmpR promoter was also omitted from the plasmid map. This cannot be said to lack function because without it the antibiotic resistance gene can't function. And without that E. coli that have incorporated plasmid cannot be selected. And without that modRNA cannot be produced.
Accordingly, the justification for excluding the SV40 enhancer-promoter sequences fails. Please comment.
3. When you say it was measured below the limit, what is the specific limit for the SV40 enhancer-promoter? Please provide the measurements obtained and the technique(s) used.
You wrote:
"*Any claims that the presence of the SV40 promoter enhancer sequence is linked to an increased risk of cancer are unfounded.*"
4. Can you provide your risk assessment that supports that statement? What studies have been performed to assess the risk of cancer due to the vaccine generally, and associated with this sequence?
5. Why didn't Pfizer-BioNTech provide the full plasmid map annotated with functional sequences? When we enter the sequence in SnapGene (Fasta file available here: https://mega.nz/file/kMxDzCZA#zJWpWr3KsfvVeQP94UBKehFkhfVft_Pg5OblO1Yt1N8), we can clearly see the SV40 enhancer-promoter-ori region.
6. Did Pfizer-BioNTech manually alter the plasmid map before providing it to Health Canada? Why did Health Canada not verify the map and instead had to learn about it from independent scientists like McKernan and Buckhaults? Also, can you please provide the software program used to produce the plasmid map disclosed by Pfizer-BioNTech? Can you name the software program you used?

7. You have quoted WHO guidelines with regards to residual DNA in biological drugs. WHO guidelines address a number of issues in that regard. For example, from the WHO Expert Committee on Biological Standardization:
(Emphasis added)
"*The complete nucleotide sequence of the plasmid DNA should be provided. In addition, the identity, source, isolation and sequence of the gene encoding the antigen(s); a description of the steps involved in the construction of the entire plasmid; a detailed functional map of the plasmid; information on the source and function of component parts of the plasmid known to have biological activities, such as origins of replication, viral/eukaryotic promoters and other expression signals and genes encoding selection markers, should be provided. A clear rationale should be provided for the use of specific regions of DNA, such as the promoter or a gene encoding a selection marker and special attention should be given to the nature of a selection marker.*
"*Any modifications to the original native sequence(s) of the antigen should be described and explained. The location of mammalian promoters in relation to antibiotic resistance genes and the use of novel promoters or inducers should be carefully considered. Certain sequences with properties of mobile elements, such as insertion sequences or retroviral-like long terminal repeats (LTRs), should be avoided. Oncogenes are not recommended unless justifi ed. It is also recommended that genes encoding enzymatic activity or a biological function be either inactivated by genetic manipulation to remove any undesirable activity, or justified. Further, although the relevance at this stage may not be understood, as part of characterization, a DNA sequence homology check of the plasmid with the international databases (e.g. the National Center for Biotechnology Information, National Institute for Health, USA, and/or other international nucleotide databases) should be performed to investigate the presence of unintended sequences of biological significance such as those encoding cellular growth functions or alternative and unanticipated reading frames. The identity of the plasmid after transfection into the bacterial cell to be used for production should be confirmed in addition to the phenotype of the cell. Representative restriction enzyme maps may be useful. Rearrangements of the plasmid within the host bacterial cell are not acceptable."*
Pfizer-BioNTech did not follow some of those guidelines with regards to providing Health Canada the full plasmid map, identifying the promoter, etc. Why is that? How is that acceptable for Health Canada? How did Health Canada engage Pfizer-BioNTech after discovering the missing data?
8. After discovering the SV40 sequence, has Health Canada engaged with Pfizer-BioNTech about other sequences which the WHO guidelines requires them to disclose, namely: SV40 poly signal and HSV-TK poly A signal (Herpes simplex virus thymidine kinase)?
9. Going further on the plasmid map (enclosed), can you comment on the Open Reading Frame (ORF) present in the plasmid that runs as long as the spike protein but in the opposite direction (green half-circle arrow). What is it? Should it be there? Why is it there? Was it identified by Pfizer-BioNTech? If no, how is this being addressed by Health Canada?
The ORF is reportedly more closely associated with a silk protein.
10. Did Pfizer-BioNTech or Health Canada examine the other possibly functional ORFs present on the plasmid?
11. Regarding the larger issue of DNA left-over impurities/contamination from the manufacturing process, can you provide us with the drug substance testing data? We'd like to see the residual DNA content per vaccine batch and the method by which the results were obtained. We're also seeking data on the fragmentation or the intactness of the RNA.

12. Finally, in reference to a previous correspondence between us, you said that Pfizer-BioNTech's Process 1 was "not plasmid-free."
a. What was the purpose of using that plasmid?
b. Was the map for that plasmid provided? Did it contain the SV40 enhancer-promoter, antibiotic resistance and other sequences?
c. Can you provide this fully annotated plasmid map?
d. How much amplification was performed from that plasmid?

We greatly appreciate your expertise and engagement on this.

Thank you and best regards,

[redacted]
The Epoch Times
195 Allstate Parkway
Markham, ON, L3R 1P8
P [redacted]
E [redacted]
www.TheEpochTimes.com

On Oct 27, 2023, at 4:35 PM, Maddison, Anna (HC/SC) wrote:

Good afternoon,

Please find below Health Canada's statement in response to your request.

Thanks and have a good evening,
Anna

Health Canada initially authorized the Pfizer-BioNTech COVID-19 mRNA vaccine in December 2020 and subsequently has authorized updated versions, including the most recent vaccine targeting the XBB Omicron subvariant in September 2023. Each assessment included a determinationthat the vaccine met the Department's stringent regulatory safety, efficacy and quality requirements for use in Canada.

As a regulator, Health Canada sets quality standards and requirements for manufacturers to follow, including providing comprehensive and detailed information

about the vaccine itself, and about the manufacturing process. In the manufacture of any vaccine, residual elements that are part of the standard manufacturing process may remain. There are strict limits and controls for the presence of these residual fragments to ensure that there is no effect on the safety or effectiveness of the vaccine.

The Pfizer-BioNTech COVID-19 vaccine does not contain simian virus 40 (SV40). The presence of the SV40 promoter enhancer sequence is not the same as the presence of the whole virus itself.

The SV40 promoter enhancer sequence was found to be a residual DNA fragment in Pfizer-BioNTech COVID-19 vaccine. The fragment is inactive, has no functional role, and was measured to be consistently below the limit required by Health Canada and other international regulators.

Any claims that the presence of the SV40 promoter enhancer sequence is linked to an increased risk of cancer are unfounded. There is also no evidence to support that the presence of the full SV40 in any vaccine increases the risk of cancer or the acceleration of cancer in individuals.

Health Canada continues to monitor the COVID-19 vaccines to ensure that they continue to meet the highest standards for safety, effectiveness and quality and that their benefits continue to outweigh any potential risks.

Anna Maddison
She, her / elle
Senior Media Relations Advisor | Communications and Public Affairs Branch
Serving Health Canada and the Public Health Agency of Canada | Government of Canada
anna.maddison@hc-sc.gc.ca | Mobile : 613-462-6617

Conseillère principale des relations avec les médias | Direction générale des affaires publiques et de communications
Au service de Santé Canada et de l'Agence de la santé publique du Canada | Gouvernement du Canada
anna.maddison@hc-sc.gc.ca | Mobile : 613-462-6617
- - -
Media | Média T: 613-957-2983 E/CE: media@hc-sc.gc.ca

From: [redacted]
Sent: Monday, October 23, 2023 1:45 PM
To: HEALTH MEDIA SANTÉ (HC/SC) <media@hc-sc.gc.ca>
Cc: [redacted]
Subject: Follow-up questions regarding DNA plasmids and SV40 sequence in COVID-19 vaccines

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My questions are whether Health Canada was aware of this paper, what the implications of the findings could be, and if they are concerned with the findings.

We know it's not peer-reviewed, but this is nevertheless the latest science, which has helped you identify the undisclosed presence of SV40. Regarding this particular issue, has Health Canada engaged with Pfizer after discovering the undisclosed presence of the SV40 DNA sequence in the Pfizer vaccine? If yes, what was the nature of the discussions? If not, why?

Thank you.

--

[redacted]
The Epoch Times
[redacted]

From: [redacted]
Sent: 2023-10-28 12:32 PM
To: Maddison, Anna (HC/SC)
Subject: Re: Health Canada - response

Hi Anna, thanks for this response. We will likely have some follow-up questions. Cheers.

On Fri, Oct 27, 2023 at 4:36 PM Maddison, Anna (HC/SC) <anna.maddison@hc-sc.gc.ca> wrote:

> Good afternoon,
>
> Please find below Health Canada's statement in response to your request.
>
> Thanks and have a good evening,
> Anna
>
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> As a regulator, Health Canada sets quality standards and requirements for manufacturers to follow, including providing comprehensive and detailed information about the vaccine itself, and about the manufacturing process. In the manufacture of any vaccine, residual elements that are part of the standard manufacturing process may remain. There are strict limits and controls for the presence of these residual fragments to ensure that there is no effect on the safety or effectiveness of the vaccine.
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> Health Canada continues to monitor the COVID-19 vaccines to ensure that they continue to meet the highest standards for safety, effectiveness and quality and that their benefits continue to outweigh any potential risks.
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Anna Maddison
She, her / elle
Senior Media Relations Advisor | Communications and Public Affairs Branch
Serving Health Canada and the Public Health Agency of Canada | Government of Canada
anna.maddison@hc-sc.gc.ca | Mobile : 613-462-6617

Conseillère principale des relations avec les médias | Direction générale des affaires publiques et de communications
Au service de Santé Canada et de l'Agence de la santé publique du Canada | Gouvernement du Canada
anna.maddison@hc-sc.gc.ca | Mobile : 613-462-6617
- - -
Media | Média T: 613-957-2983 E/CE: media@hc-sc.gc.ca

From: [redacted]
Sent: Monday, October 23, 2023 1:45 PM
To: HEALTH MEDIA SANTÉ (HC/SC) <media@hc-sc.gc.ca>
Cc: [redacted]
Subject: Follow-up questions regarding DNA plasmids and SV40 sequence in COVID-19 vaccines

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My questions are whether Health Canada was aware of this paper, what the implications of the findings could be, and if they are concerned with the findings.

We know it's not peer-reviewed, but this is nevertheless the latest science, which has helped you identify the undisclosed presence of SV40. Regarding this particular issue, has Health Canada engaged with Pfizer after discovering the undisclosed presence of the SV40 DNA sequence in the Pfizer vaccine? If yes, what was the nature of the discussions? If not, why?

Thank you.

--
[redacted] The Epoch Times
[redacted]

--

[redacted] The Epoch Times

From: Maddison, Anna (HC/SC)
Sent: 2023-10-27 4:36 PM
To: [redacted]
Cc:
Subject: Health Canada - response

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Thanks and have a good evening,
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She, her / elle
Senior Media Relations Advisor | Communications and Public Affairs Branch
Serving Health Canada and the Public Health Agency of Canada | Government of Canada
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Conseillère principale des relations avec les médias | Direction générale des affaires publiques et

de communications
Au service de Santé Canada et de l'Agence de la santé publique du Canada | Gouvernement du Canada
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- - -
Media | Média T: 613-957-2983 E/CE: media@hc-sc.gc.ca

From: [redacted]
Sent: Monday, October 23, 2023 1:45 PM
To: HEALTH MEDIA SANTÉ (HC/SC) <media@hc-sc.gc.ca>
Cc: [redacted]
Subject: Follow-up questions regarding DNA plasmids and SV40 sequence in COVID-19 vaccines

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Thank you.

--
[redacted] The Epoch Times
[redacted]

From: [redacted]
Sent: 2023-10-23 2:58 PM
To: Maddison, Anna (HC/SC)
Subject: Re: Follow-up questions regarding DNA plasmids and SV40 sequence in COVID-19 vaccines

---

Thank you, Anna. Always appreciated.

On Mon, Oct 23, 2023 at 2:42 PM Maddison, Anna (HC/SC) <anna.maddison@hc-sc.gc.ca> wrote:

> Hi [redacted],
>
> Request received. We'll get back to you with a response to your questions as soon as we can.
>
> Thanks,
> Anna
>
> ---
> **Anna Maddison**
> She, her / elle
> Senior Media Relations Advisor | Communications and Public Affairs Branch
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> Conseillère principale des relations avec les médias | Direction générale des affaires publiques et de communications
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> - - -
> Media | Média T: 613-957-2983 E/CE: media@hc-sc.gc.ca
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> **From:** [redacted]
> **Sent:** Monday, October 23, 2023 1:45 PM
> **To:** HEALTH MEDIA SANTÉ (HC/SC) <media@hc-sc.gc.ca>
> **Cc:** [redacted]
> **Subject:** Follow-up questions regarding DNA plasmids and SV40 sequence in COVID-19 vaccines
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Thank you.

--

[redacted] The Epoch Times

[redacted]

--

[redacted] The Epoch Times

[redacted]

From: Maddison, Anna (HC/SC)
Sent: 2023-10-23 2:42 PM
To: [redacted]
Cc: [redacted]
Subject: RE: Follow-up questions regarding DNA plasmids and SV40 sequence in COVID-19 vaccines

---

Hi [redacted]

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She, her / elle
Senior Media Relations Advisor | Communications and Public Affairs Branch
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Conseillère principale des relations avec les médias | Direction générale des affaires publiques et de communications
Au service de Santé Canada et de l'Agence de la santé publique du Canada | Gouvernement du Canada
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- - -
Media | Média T: 613-957-2983 E/CE: media@hc-sc.gc.ca

From: [redacted]
Sent: Monday, October 23, 2023 1:45 PM
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Cc: [redacted]
Subject: Follow-up questions regarding DNA plasmids and SV40 sequence in COVID-19 vaccines

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Thank you.

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[redacted] The Epoch Times

[redacted]

From: [redacted]
Sent: 2023-10-23 1:45 PM
To: HEALTH MEDIA SANTÉ (HC/SC)
Cc: [redacted]
Subject: Follow-up questions regarding DNA plasmids and SV40 sequence in COVID-19 vaccines

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Categories: Dispatched

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Thank you.

--

[redacted] The Epoch Times
[redacted]

From: [redacted]
Sent: 2023-08-18 3:00 PM
To: Maddison, Anna (HC/SC)
Subject: Re: Health Canada - response

Thank you very much.

[redacted]
The Epoch Times
195 Allstate Parkway
Markham, ON, L3R 1P8
P [redacted]
E [redacted]
www.TheEpochTimes.com

On Aug 18, 2023, at 2:42 PM, Maddison, Anna (HC/SC) <anna.maddison@hc-sc.gc.ca> wrote:

Hi [redacted],

Please find below Health Canada's response to your latest follow up questions.

Thank you,
Anna

Have you tried to independently verify other findings made by the scientists? Are you able to disprove Buckhaults' latest assertion, without relying on old assurances given by the manufacturer?

As noted previously, based on our evaluation of the data and scientific information for the vaccine, we have concluded that the risk/benefit profile continues to support the use of the Pfizer-BioNTech vaccine.

Health Canada does not rely on the conclusions provided by vaccine manufacturers. Health Canada conducts an in-depth independent review of the required evidence provided by the manufacturer to ensure that our high standards for safety, efficacy and quality are met. The Department works in close collaboration with international agencies including other regulators and the World Health Organization to ensure that vaccines available are safe and effective.

Are you currently assessing what would be the impact on the health of Canadians if Buckhaults is right about there being a genome modification?

As previously noted, the presence of residual plasmid DNA in the mRNA COVID-19 vaccines does not change Health Canada's assessments of the safety of these vaccines. In addition, scientists have been working to develop plasmid DNA based vaccines against infectious diseases since the 1990s. Although chromosomal integration of the plasmid DNA was initially a major theoretical concern, the data obtained to date do not support this concern.

Furthermore, the plasmid used to prepare the Pfizer-BioNTech vaccine does not contain adenovirus virus sequences, and there is no peer reviewed evidence that linearized or fragmented DNA is capable of translocating to the nucleus of cells.

Additional details concerning the safety of plasmid DNA can be found in the following guidance documents:

- US FDA Guidance for Industry Considerations for Plasmid DNA Vaccines for Infectious Disease Indications
- WHO TRS N°1028, Annex2, Guidelines on the quality, safety and efficacy of plasmid DNA vaccines

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Conseillère principale des relations avec les médias | Direction générale des affaires publiques et de communications
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- - -
Media | Média T: 613-957-2983 E/CE: media@hc-sc.gc.ca

From: [redacted]
Sent: Wednesday, August 16, 2023 12:27 PM
To: HEALTH MEDIA SANTÉ (HC/SC) <media@hc-sc.gc.ca>
Subject: Genome modification

Good day,

Scientist Dr. Buckhaults said yesterday "i guarantee you there has been genome modification" in reference to his latest findings surrounding covid vax contamination.
https://twitter.com/P_J_Buckhaults/status/1691596093422006333

I know Health Canada's position on the matter, which you relayed to us in recent weeks. But you've also admitted having been unaware of the presence of SV40 in the vax, until McKernan and Buckhaults made the independent finding.

Have you tried to independently verify other findings made by the scientists?

Are you able to disprove Buckhaults' latest assertion, without relying on old assurances given by the manufacturer?

Are you currently assessing what would be the impact on the health of Canadians if Buckhaults is right about there being a genome modification?

Thank you and best regards,

[redacted]
The Epoch Times
195 Allstate Parkway
Markham, ON, L3R 1P8
P [redacted]
E [redacted]
www.TheEpochTimes.com

From: Maddison, Anna (HC/SC)
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Subject: Health Canada - response

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[redacted]
The Epoch Times
195 Allstate Parkway

Markham, ON, L3R 1P8
P [redacted]
E [redacted]
www.TheEpochTimes.com

From: [redacted]
Sent: 2023-08-11 3:45 PM
To: Maddison, Anna (HC/SC)
Subject: Re: Health Canada - response

Thank you very much.

[redacted]
The Epoch Times
195 Allstate Parkway
Markham, ON, L3R 1P8
P [redacted]
E [redacted]
www.TheEpochTimes.com

On Aug 10, 2023, at 12:09 PM, Maddison, Anna (HC/SC) <anna.maddison@hc-sc.gc.ca> wrote:

Hi [redacted] and [redacted],

Please find below Health Canada's response to your follow up questions.

Thanks and take care,
Anna

PCR amplification of the plasmid materially alters the nature of the contaminant. PCR often amplifies molecules millions to billions of times. This would make the residual DNA being used for IVT to contain only the Spike sequence and the T7 promoter but eliminate the SV40 sequences and the rest of the 7810 base pair plasmid. While steps are in place to remove these dsDNA's, the documentation given to the EMA shows this step lacks validation and has high variance (815X across 10 vials). Has Health Canada produced any peer reviewed evidence or data regarding your monitoring of this step?

Health Canada cannot comment on information provided by sponsors to other regulatory authorities. The data generated to quantify the residual plasmid DNA was obtained using approved validated methods submitted to Health Canada by the sponsor. These data demonstrated that the residual DNA content in the final product was consistently below the limit approved by Health Canada. The limit for the

residual DNA is controlled as not more than 10 ng/human dose, which is in line with the World Health Organization's recommendation concerning residual DNA in biological drugs.

How does Health Canada evaluate if a PCR assay is fit for purpose if the primers are proprietary? If the qPCR primers used to evaluate dsDNA contamination lie outside of the PCR amplification Pfizer is using to amplify their plasmid DNA, then these primers will report a false result. Given the Pfizer sequence is public and often mandated, why are qPCR primers used to evaluate the dsDNA contamination proprietary? Are any CT values for this dsDNA assessment available for public review?

Please note that the manufacturer does provide proprietary information and data to Health Canada for evaluation, which includes the type of methods, or details of the methods, used for manufacturing and control. The proprietary nature of the information indicates that this information is not disclosed publicly.

DNA-based vectors are very analogous to DNA adenovirus vectors. And there is evidence of SV40 virus integrating into genomes: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2913896/. There is also ample evidence SV40 plasmids containing the same elements in the vaccines can integrate: https://journals.asm.org/doi/10.1128/JVI.68.2.787-796.1994?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed. Has Health Canada performed any work to assess if this genome integration is happening? Can Health Canada or manufacturers prove without the shadow of a doubt it isn't?

The Pfizer DNA plasmid used to produce the COVID-19 vaccine is distinct from DNA adenovirus vectors in sequence and biological functions. Furthermore, the Pfizer plasmid does not contain sequences corresponding to SV40 proteins studied in the paper cited. Therefore, the integration mechanisms described are not applicable.

Anna Maddison
She, her / elle
Senior Media Relations Advisor | Communications and Public Affairs Branch
Serving Health Canada and the Public Health Agency of Canada | Government of Canada
anna.maddison@hc-sc.gc.ca | Mobile : 613-462-6617

Conseillère principale des relations avec les médias | Direction générale des affaires publiques et de communications
Au service de Santé Canada et de l'Agence de la santé publique du Canada | Gouvernement du Canada
anna.maddison@hc-sc.gc.ca | Mobile : 613-462-6617
- - -
Media | Média T: 613-957-2983 E/CE: media@hc-sc.gc.ca

From: [redacted]
Sent: Monday, July 31, 2023 6:21 PM
To: Maddison, Anna (HC/SC) <anna.maddison@hc-sc.gc.ca>

Cc: [redacted]
Subject: Re: Health Canada - response

Hi Anna,

Thank you very much for the detailed response. [redacted] I will send you what is hopefully one last round of questions. We are grateful for your time and that of the specialists going over this.

Your answer:
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Follow-up question:
PCR amplification of the plasmid materially alters the nature of the contaminant. PCR often amplifies molecules millions to billions of times. This would make the residual DNA being used for IVT to contain only the Spike sequence and the T7 promoter but eliminate the SV40 sequences and the rest of the 7810 base pair plasmid. While steps are in place to remove these dsDNA's, the documentation given to the EMA shows this step lacks validation and has high variance (815X across 10 vials). Has Health Canada produced any peer reviewed evidence or data regarding your monitoring of this step?

Your answer:
Testing data analyzed by Health Canada, as well as the PCR primers and probes used, are proprietary information of the vaccine manufacturer. They are not public information. However, the methods used for measuring residual DNA fragments were appropriately validated by the manufacturer and evaluated as fit for purpose by Health Canada. In addition, all Pfizer COVID-19 vaccine commercial batches released in Canada complied with the requirements approved by Health Canada, including the residual DNA.

Follow-up question:
How does Health Canada evaluate if a PCR assay is fit for purpose if the primers are proprietary? If the qPCR primers used to evaluate dsDNA contamination lie outside of the PCR amplification Pfizer is using to amplify their plasmid DNA, then these primers will report a false result. Given the Pfizer sequence is public and often

mandated, why are qPCR primers used to evaluate the dsDNA contamination proprietary? Are any CT values for this dsDNA assessment available for public review?

Your answer:
https://www.urmc.rochester.edu/labs/dean/projects/nuclear-targeting-of-plasmids-and-protein-dna-comp.aspx

The information on the above website suggests that intact plasmids containing the SV40 enhancer sequence can translocate to the nucleus of cells in culture. However, this information has not been peer reviewed, hence its validity has not been verified.

In addition, the DNA plasmid used for the Pfizer vaccine production is linearized, degraded, and reduced in quantity through additional steps. There is no peer reviewed evidence that linearized or fragmented DNA is capable of translocating to the nucleus of cells.

Follow-up comment:
The work of David Dean has been peer reviewed and published. The web link was just a general reference.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4152905/
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4150867/
https://www.cell.com/molecular-therapy-family/molecular-therapy/fulltext/S1525-0016(16)30801-2
https://www.jbc.org/article/S0021-9258(20)38527-6/fulltext

Dean demonstrates that the 72bp SV40 enhancer is all that is required to recruit transcription factors that localize DNA to the nucleus.

Your answer:
https://www.nature.com/articles/s41434-021-00278-2

The paper cited provides evidence that adenovirus vectors have the potential to integrate into genomic DNA. The plasmid used to prepare the Pfizer vaccine does not contain adenovirus virus sequences. Furthermore, as noted in the response to the previous question, there is no evidence that fragmented DNA is capable of translocating to the nucleus of cells.-

Follow-up question:
DNA-based vectors are very analogous to DNA adenovirus vectors.

And there is evidence of SV40 virus integrating into genomes:
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On Jul 29, 2023, at 1:34 AM, [redacted] wrote:

---------- Forwarded message ---------
From: **Maddison, Anna (HC/SC)** <anna.maddison@hc-sc.gc.ca>
Date: Fri, Jul 28, 2023 at 2:36 PM
Subject: Health Canada - response
To: [redacted]

Good afternoon [redacted],

Please find below the response to your follow up questions. My apologies for the delay in getting back to you.

Thanks and have a good afternoon,
Anna

Can Health Canada confirm that the Pfizer trial used a plasmid-free manufacturing method known as 'Process 1,' and then after the trial scaled up production with plasmids in a manufacturing

process known as 'Process 2'?
If that is the case, how can Health Canada be assured the Pfizer vaccines are safe and effective if the trials didn't use plasmid-contaminated vaccines?

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Health Canada cannot comment on information provided to another regulatory authority. Health Canada expects sponsors to identify any biologically functional DNA sequences within a plasmid (such as an SV40 enhancer) at the time of submission. Although the full DNA sequence of the Pfizer plasmid was provided at the time of initial filing, the sponsor did not specifically identify SV40 sequence. When the presence of the SV40 enhancer was raised publicly by McKernan and Buckhaults, it was possible for Health Canada to confirm the presence of the enhancer based on the plasmid DNA sequence submitted by Pfizer against the published SV40 enhancer sequence.

As mentioned in response to the first question, the residual plasmid DNA is present in the final product as DNA fragments, due to the enzyme digestion step in the downstream process. As such, the original

risk benefit analysis that supported the initial approval of the Pfizer vaccine continues to be valid.

Finally, information contained here indicates that plasmids are able to enter the nuclei of cells. Is it inaccurate?
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- - -
Media | Média T: 613-957-2983 E/CE: hc.media.sc@canada.ca

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[redacted] The Epoch Times

[redacted]

<~WRD0212.jpg>

From: Maddison, Anna (HC/SC)
Sent: 2023-08-10 12:09 PM
To: [redacted]
Cc: [redacted]
Subject: Health Canada - response

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Dean demonstrates that the 72bp SV40 enhancer is all that is required to recruit transcription factors that localize DNA to the nucleus.

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On Jul 29, 2023, at 1:34 AM, [redacted] wrote:

---------- Forwarded message ---------
From: **Maddison, Anna (HC/SC)** <anna.maddison@hc-sc.gc.ca>
Date: Fri, Jul 28, 2023 at 2:36 PM
Subject: Health Canada - response
To: [redacted]

Good afternoon [redacted]

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Thanks and have a good afternoon,
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Finally, information contained here indicates that plasmids are able to enter the nuclei of cells. Is it inaccurate?
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- - -
Media | Média T: 613-957-2983 E/CE: hc.media.sc@canada.ca

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[redacted] The Epoch Times

From: [redacted]
Sent: 2023-08-09 2:32 PM
To: Maddison, Anna (HC/SC)
Subject: Re: Health Canada - response

Good afternoon, Anna.

Just to be clear, are you confirming that SV40 Enhancer sequence is contained within the COVID-19 vaccines, and that Pfizer did not present this fact to Health Canada? If so, could you also provide a statement on claims that have been made regarding SV40 and its connection to cancers? Thanks.

On Fri, Jul 28, 2023 at 2:36 PM Maddison, Anna (HC/SC) <anna.maddison@hc-sc.gc.ca> wrote:

> Good afternoon [redacted]
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The paper cited provides evidence that adenovirus vectors have the potential to integrate into genomic DNA. The plasmid used to prepare the Pfizer vaccine does not contain adenovirus virus sequences. Furthermore, as noted in the response to the previous question, there is no evidence that fragmented DNA is capable of translocating to the nucleus of cells.-

---
Anna Maddison
She, her / elle
Senior Media Relations Advisor | Communications and Public Affairs Branch
Serving Health Canada and the Public Health Agency of Canada | Government of Canada
anna.maddison@canada.ca | Mobile : 613-462-6617

Conseillère principale des relations avec les médias | Direction générale des affaires publiques et de communications
Au service de Santé Canada et de l'Agence de la santé publique du Canada | Gouvernement du Canada
anna.maddison@canada.ca | Mobile : 613-462-6617

- - -
Media | Média T: 613-957-2983 E/CE: hc.media.sc@canada.ca

--
[redacted] The Epoch Times

From: [redacted]
Sent: 2023-07-31 6:21 PM
To: Maddison, Anna (HC/SC)
Cc: [redacted]
Subject: Re: Health Canada - response

Follow Up Flag: Follow up
Flag Status: Flagged

Hi Anna,

Thank you very much for the detailed response.[redacted] I will send you what is hopefully one last round of questions. We are grateful for your time and that of the specialists going over this.

Your answer:
Pfizer's "process 1" uses PCR-amplified DNA to produce the COVID-19 vaccine. Although the PCR amplification reaction uses linearized plasmid DNA as template, not intact plasmid, Pfizer "process 1" derived clinical materials are not plasmid-free. The commercial batches of Pfizer's COVID-19 vaccine are produced using "process 2," which only uses linearized plasmid DNA (i.e., no PCR amplification) to produce the vaccine. Both "process 1" and "process 2" include a step to degrade the DNA template into fragments, followed by steps to reduce the quantity of DNA in the final product to below the approved limit. The approved limit for residual DNA is the same for "process 1" and "process 2," and is in line with the recommendation from the World Health Organization. The comparability of the vaccine produced by these two processes was demonstrated based on their biological, chemical and physical characteristics. Therefore, efficacy and safety demonstrated using clinical batches manufactured using "process 1" are also applicable to commercial batches produced using "process 2".

Follow-up question:
PCR amplification of the plasmid materially alters the nature of the contaminant. PCR often amplifies molecules millions to billions of times. This would make the residual DNA being used for IVT to contain only the Spike sequence and the T7 promoter but eliminate the SV40 sequences and the rest of the 7810 base pair plasmid. While steps are in place to remove these dsDNA's, the documentation given to the EMA shows this step lacks validation and has high variance (815X across 10 vials). Has Health Canada produced any peer reviewed evidence or data regarding your monitoring of this step?

Your answer:
Testing data analyzed by Health Canada, as well as the PCR primers and probes used, are proprietary information of the vaccine manufacturer. They are not public information. However, the methods used for measuring residual DNA fragments were appropriately validated by the manufacturer and evaluated as fit for purpose by Health Canada. In addition, all Pfizer COVID-19 vaccine commercial batches released in Canada complied with the requirements approved by Health Canada, including the residual DNA.

Follow-up question:

How does Health Canada evaluate if a PCR assay is fit for purpose if the primers are proprietary? If the qPCR primers used to evaluate dsDNA contamination lie outside of the PCR amplification Pfizer is using to amplify their plasmid DNA, then these primers will report a false result. Given the Pfizer sequence is public and often mandated, why are qPCR primers used to evaluate the dsDNA contamination proprietary? Are any CT values for this dsDNA assessment available for public review?

Your answer:
https://www.urmc.rochester.edu/labs/dean/projects/nuclear-targeting-of-plasmids-and-protein-dna-comp.aspx

The information on the above website suggests that intact plasmids containing the SV40 enhancer sequence can translocate to the nucleus of cells in culture. However, this information has not been peer reviewed, hence its validity has not been verified.

In addition, the DNA plasmid used for the Pfizer vaccine production is linearized, degraded, and reduced in quantity through additional steps. There is no peer reviewed evidence that linearized or fragmented DNA is capable of translocating to the nucleus of cells.

Follow-up comment:
The work of David Dean has been peer reviewed and published. The web link was just a general reference.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4152905/
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4150867/
https://www.cell.com/molecular-therapy-family/molecular-therapy/fulltext/S1525-0016(16)30801-2
https://www.jbc.org/article/S0021-9258(20)38527-6/fulltext

Dean demonstrates that the 72bp SV40 enhancer is all that is required to recruit transcription factors that localize DNA to the nucleus.

Your answer:
https://www.nature.com/articles/s41434-021-00278-2

The paper cited provides evidence that adenovirus vectors have the potential to integrate into genomic DNA. The plasmid used to prepare the Pfizer vaccine does not contain adenovirus virus sequences. Furthermore, as noted in the response to the previous question, there is no evidence that fragmented DNA is capable of translocating to the nucleus of cells.-

Follow-up question:
DNA-based vectors are very analogous to DNA adenovirus vectors.

And there is evidence of SV40 virus integrating into genomes:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2913896/

There is also ample evidence SV40 plasmids containing the same elements in the vaccines can integrate:

https://journals.asm.org/doi/10.1128/JVI.68.2.787-796.1994?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

Has Health Canada performed any work to assess if this genome integration is happening? Can Health Canada or manufacturers prove without the shadow of a doubt it isn't?

Thank you and best regards,

[redacted]
The Epoch Times
195 Allstate Parkway
Markham, ON, L3R 1P8
P [redacted]
E [redacted]
www.TheEpochTimes.com

On Jul 29, 2023, at 1:34 AM, [redacted] wrote:

---------- Forwarded message ---------
From: **Maddison, Anna (HC/SC)**
Date: Fri, Jul 28, 2023 at 2:36 PM
Subject: Health Canada - response
To: [redacted]

Good afternoon [redacted]

Please find below the response to your follow up questions. My apologies for the delay in getting back to you.

Thanks and have a good afternoon,
Anna

Can Health Canada confirm that the Pfizer trial used a plasmid-free manufacturing method known as 'Process 1,' and then after the trial scaled up production with plasmids in a manufacturing process known as 'Process 2'?

If that is the case, how can Health Canada be assured the Pfizer vaccines are safe and effective if the trials didn't use plasmid-contaminated vaccines?

Pfizer's "process 1" uses PCR-amplified DNA to produce the COVID-19 vaccine. Although the PCR amplification reaction uses linearized plasmid DNA as template, not intact plasmid, Pfizer "process 1" derived clinical materials are not plasmid-free. The commercial batches of Pfizer's COVID-19 vaccine are produced using "process 2," which only uses linearized plasmid DNA (i.e., no PCR amplification) to produce the vaccine. Both "process 1" and "process 2" include a step to degrade the DNA template into fragments, followed by steps to reduce the quantity of DNA in the final product to below the approved limit. The approved limit for residual DNA is the same for "process 1" and "process 2," and is in line with the recommendation from the World Health Organization. The comparability of the vaccine produced by these two processes was demonstrated based on their biological, chemical and physical characteristics. Therefore, efficacy and safety demonstrated using clinical batches manufactured using "process 1" are also applicable to commercial batches produced using "process 2".

Can you point to the testing data analyzed by Health Canada on the issue? Is it public? Also, are the PCR primers and probes used to make this assessment public?

Testing data analyzed by Health Canada, as well as the PCR primers and probes used, are proprietary information of the vaccine manufacturer. They are not public information. However, the methods used for measuring residual DNA fragments were appropriately validated by the manufacturer and evaluated as fit for purpose by Health Canada. In addition, all Pfizer COVID-19 vaccine commercial batches released in Canada complied with the requirements approved by Health Canada, including the residual DNA.

McKernan asserts that the Pfizer vaccines contain an SV40 Enhancer sequence that is commonly used for gene therapy, but this sequence was not disclosed to the EMA. Do you have information on that matter?

Health Canada cannot comment on information provided to another regulatory authority. Health Canada expects sponsors to identify any biologically functional DNA sequences within a plasmid (such as an SV40 enhancer) at the time of submission. Although the full DNA sequence of the Pfizer plasmid was provided at the time of initial filing, the sponsor did not specifically identify SV40 sequence. When the presence of the SV40 enhancer was raised publicly by McKernan and Buckhaults, it was possible for Health Canada to confirm the presence of the enhancer based on the plasmid DNA sequence submitted by Pfizer against the published SV40 enhancer sequence.

As mentioned in response to the first question, the residual plasmid DNA is present in the final product as DNA fragments, due to the enzyme digestion step in the downstream process. As such, the original risk benefit analysis that supported the initial approval of the Pfizer vaccine continues to be valid.

Finally, information contained here indicates that plasmids are able to enter the nuclei of cells. Is it inaccurate?
https://www.urmc.rochester.edu/labs/dean/projects/nuclear-targeting-of-plasmids-and-protein-dna-comp.aspx

The information on the above website suggests that intact plasmids containing the SV40 enhancer sequence can translocate to the nucleus of cells in culture. However, this information has not been peer reviewed, hence its validity has not been verified. In addition, the DNA plasmid used for the Pfizer vaccine production is linearized, degraded, and reduced in quantity through additional steps. There is no peer reviewed evidence that linearized or fragmented DNA is capable of translocating to the nucleus of cells.

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- - -
Media | Média T: 613-957-2983 E/CE: hc.media.sc@canada.ca

--
[redacted] The Epoch Times

From: Maddison, Anna (HC/SC)
Sent: 2023-07-28 2:36 PM
To: [redacted]
Subject: Health Canada - response

Good afternoon [redacted]

Please find below the response to your follow up questions. My apologies for the delay in getting back to you.

Thanks and have a good afternoon,
Anna

Can Health Canada confirm that the Pfizer trial used a plasmid-free manufacturing method known as 'Process 1,' and then after the trial scaled up production with plasmids in a manufacturing process known as 'Process 2'?
If that is the case, how can Health Canada be assured the Pfizer vaccines are safe and effective if the trials didn't use plasmid-contaminated vaccines?

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Au service de Santé Canada et de l'Agence de la santé publique du Canada | Gouvernement du Canada
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- - -
Media | Média T: 613-957-2983 E/CE: hc.media.sc@canada.ca

From: [redacted]
Sent: 2023-07-19 5:19 PM
To: Maddison, Anna (HC/SC)
Subject: Re: Follow-up questions for article on DNA plasmids and COVID-19 vaccines

---

That's perfectly fine. Thanks, Anna.

On Wed, Jul 19, 2023 at 4:25 PM Maddison, Anna (HC/SC) <anna.maddison@hc-sc.gc.ca> wrote:

> Thanks, follow up questions received.
>
> Given the number of new questions, we will need some time to get back to you with the requested information. I'll do my best to get back to you as soon as I can, but it might not be until early next week.
>
> Thanks,
> Anna
>
> **From:** [redacted]
> **Sent:** Wednesday, July 19, 2023 4:11 PM
> **To:** Maddison, Anna (HC/SC) <anna.maddison@hc-sc.gc.ca>
> **Subject:** Follow-up questions for article on DNA plasmids and COVID-19 vaccines
>
> Hi Anna,
>
> I hope you are well. I was wondering if Health Canada could provide answers to these follow-up questions on DNA plasmids and the COVID-19 vaccine:
>
> -Can Health Canada confirm that the Pfizer trial used a plasmid-free manufacturing method known as 'Process 1,' and then after the trial scaled up production with plasmids in a manufacturing process known as 'Process 2'?
>
> -If that is the case, how can Health Canada be assured the Pfizer vaccines are safe and effective if the trials didn't use plasmid-contaminated vaccines?
>
> -Can you point to the testing data analyzed by Health Canada on the issue? Is it public? Also, are the PCR primers and probes used to make this assessment public?

-McKernan asserts that the Pfizer vaccines contain an SV40 Enhancer sequence that is commonly used for gene therapy, but this sequence was not disclosed to the EMA. Do you have information on that matter?

-Finally, information contained here indicates that plasmids are able to enter the nuclei of cells. Is it inaccurate?
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-Also this paper discusses genomic integration and seems to contradict your statement about it not being of concern. Is it inaccurate?
https://www.nature.com/articles/s41434-021-00278-2

Thank you for your time on this.
--
[redacted] The Epoch Times
[redacted]

--
[redacted] The Epoch Times
[redacted]

From: Maddison, Anna (HC/SC)
Sent: 2023-07-19 4:26 PM
To: [redacted]
Subject: RE: Follow-up questions for article on DNA plasmids and COVID-19 vaccines

---

Thanks, follow up questions received.

Given the number of new questions, we will need some time to get back to you with the requested information. I'll do my best to get back to you as soon as I can, but it might not be until early next week.

Thanks,
Anna

From: [redacted]
Sent: Wednesday, July 19, 2023 4:11 PM
To: Maddison, Anna (HC/SC) <anna.maddison@hc-sc.gc.ca>
Subject: Follow-up questions for article on DNA plasmids and COVID-19 vaccines

Hi Anna,

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https://www.nature.com/articles/s41434-021-00278-2

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--
[redacted] The Epoch Times
[redacted]

From: [redacted]
Sent: 2023-07-19 4:11 PM
To: Maddison, Anna (HC/SC)
Subject: Follow-up questions for article on DNA plasmids and COVID-19 vaccines

---

Hi Anna,

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https://www.nature.com/articles/s41434-021-00278-2

Thank you for your time on this.

--

[redacted] The Epoch Times

[redacted]

From: [redacted]
Sent: 2023-07-19 2:13 PM
To: Maddison, Anna (HC/SC)
Subject: Re: Health Canada - response

Thanks for this, Anna!

On Wed, Jul 19, 2023 at 2:01 PM Maddison, Anna (HC/SC) <anna.maddison@hc-sc.gc.ca> wrote:

> Hi [redacted],
>
> Thanks for your patience. Please find below Health Canada's response to your enquiry.
>
> Thaks,
> Anna
>
> ---
>
> ***I was wondering if Health Canada/PHAC have checked COVID-19 vaccine vials for plasmid contamination if they are aware of this issue and are tracking it, and what the impacts on health and human DNA could be if the findings of McKernan and Buckhaults are correct.***
>
> Plasmids are an essential starting material for the production of mRNA vaccines. During the downstream process in mRNA vaccine manufacturing, the plasmid DNA is digested with enzymes to small fragments, and further removed to a level of not more than 10 ng/human dose, which is in line with the World Health Organization's recommendation concerning residual DNA in biological drugs. The DNA is digested with enzymes post-transcription.
>
> Health Canada was aware of the presence of residual plasmid DNA as a process-related impurity during review and prior to the authorization of the mRNA COVID-19 vaccines. In addition, the release testing data for every COVID-19 vaccine lot released into the Canadian market were reviewed and deemed to meet the requirements approved by Health Canada. Furthermore, different assays assessing the same vaccine property, or even the same assay being performed in different laboratories, may generate different results.
>
> It is important to assess the results using the authorized validated assays performed by the vaccine manufacturers to ensure that the quality of commercial vaccine lots are comparable to lots shown to be safe and efficacious in clinical studies.
>
> ***We are aware HC has previously stated that the mRNA vaccines are not "gene altering therapies," but would DNA plasmid contamination on that reported scale change that assessment?***
>
> The presence of residual plasmid DNA in the mRNA COVID-19 vaccines does not change the safety assessment of these vaccines by Health Canada. In addition, scientists have been working to develop plasmid DNA based vaccines against infectious diseases since the 1990s. Although chromosomal integration of the plasmid DNA was initially a major theoretical concern, the data obtained to date do not support this concern. Additional details concerning the safety of plasmid DNA can be found in the following guidance documents:

- US FDA Guidance for Industry Considerations for Plasmid DNA Vaccines for Infectious Disease Indications
- WHO TRS N°1028, Annex2, Guidelines on the quality, safety and efficacy of plasmid DNA vaccines

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Anna Maddison
She, her / elle
Senior Media Relations Advisor | Communications and Public Affairs Branch
Serving Health Canada and the Public Health Agency of Canada | Government of Canada
anna.maddison@canada.ca | Mobile : 613-462-6617

Conseillère principale des relations avec les médias | Direction générale des affaires publiques et de communications
Au service de Santé Canada et de l'Agence de la santé publique du Canada | Gouvernement du Canada
anna.maddison@canada.ca | Mobile : 613-462-6617
- - -
Media | Média T: 613-957-2983 E/CE: hc.media.sc@canada.ca

--

[redacted] The Epoch Times

From: Maddison, Anna (HC/SC)
Sent: 2023-07-19 2:02 PM
To: [redacted]
Subject: Health Canada - response

Hi [redacted],

Thanks for your patience. Please find below Health Canada's response to your enquiry.

Thaks,
Anna

I was wondering if Health Canada/PHAC have checked COVID-19 vaccine vials for plasmid contamination if they are aware of this issue and are tracking it, and what the impacts on health and human DNA could be if the findings of McKernan and Buckhaults are correct.

Plasmids are an essential starting material for the production of mRNA vaccines. During the downstream process in mRNA vaccine manufacturing, the plasmid DNA is digested with enzymes to small fragments, and further removed to a level of not more than 10 ng/human dose, which is in line with the World Health Organization's recommendation concerning residual DNA in biological drugs. The DNA is digested with enzymes post-transcription.

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It is important to assess the results using the authorized validated assays performed by the vaccine manufacturers to ensure that the quality of commercial vaccine lots are comparable to lots shown to be safe and efficacious in clinical studies.

We are aware HC has previously stated that the mRNA vaccines are not "gene altering therapies," but would DNA plasmid contamination on that reported scale change that assessment?

The presence of residual plasmid DNA in the mRNA COVID-19 vaccines does not change the safety assessment of these vaccines by Health Canada. In addition, scientists have been working to develop plasmid DNA based vaccines against infectious diseases since the 1990s. Although chromosomal integration of the plasmid DNA was initially a major theoretical concern, the data obtained to date do not support this concern. Additional details concerning the safety of plasmid DNA can be found in the following guidance documents:

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- - -
Media | Média T: 613-957-2983 E/CE: hc.media.sc@canada.ca

From: [redacted]
Sent: 2023-07-18 3:03 PM
To: Maddison, Anna (HC/SC)
Subject: Re: Questions for article on DNA plasmid contamination of COVID-19 vaccines

---

Hi Anna. No worries, I can extend the deadline. Thanks.

On Tue, Jul 18, 2023 at 3:02 PM Maddison, Anna (HC/SC) <anna.maddison@hc-sc.gc.ca> wrote:

> Hi again [redacted]
>
> I just wanted to let you know that unfortunately we won't be able to get back to you with a response today.
>
> If you are still interested in receiving a response after your deadline, I'll continue working on it and will do my best to get back to you as soon as I can.
>
> Thanks,
> Anna
>
> **From:** [redacted]
> **Sent:** Monday, July 17, 2023 12:39 PM
> **To:** Maddison, Anna (HC/SC) <anna.maddison@hc-sc.gc.ca>
> **Subject:** Re: Questions for article on DNA plasmid contamination of COVID-19 vaccines
>
> [redacted] Thank you, Anna.
>
> [redacted]
>
> On Mon, Jul 17, 2023 at 12:38 PM Maddison, Anna (HC/SC) <anna.maddison@hc-sc.gc.ca> wrote:
>
> > Hi [redacted] – confirming receipt of your request below.
> >
> > What is your deadline?
> >
> > Thanks,
> > Anna

Anna Maddison
She, her / elle
Senior Media Relations Advisor | Communications and Public Affairs Branch
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- - -
Media | Média T: 613-957-2983 E/CE: media@hc-sc.gc.ca

From: [redacted]
Sent: Monday, July 17, 2023 10:21 AM
To: HEALTH MEDIA SANTÉ (HC/SC) <media@hc-sc.gc.ca>
Subject: Questions for article on DNA plasmid contamination of COVID-19 vaccines

Hello,

I am writing an article for the Epoch Times on the issue of DNA plasmid contamination in the COVID-19 vaccines. Microbiologist Kevin McKernan initially tested some of the COVID vaccine vials and discovered double-stranded DNA plasmids floating around, and warned that this may mean the COVID-19 vaccines have the ability to alter the human genome.

McKernan's article in preprint: "Sequencing of bivalent Moderna and Pfizer mRNA vaccines reveals nanogram to microgram quantities of expression vector dsDNA per dose"
https://osf.io/b9t7m/

McKernan's presentation of his findings to the FDAhttps://twitter.com/TheChiefNerd/status/1669443898547003399

Then on July 12, molecular biologist Phillip J. Buckhaults from the University of South Carolina came to the same conclusions as McKernan and posted his findings on Twitter: "dear @US_FDA there is plasmid dna in the pfizer vaccine. about 1 or 2 million copies per ul. this is probably not a problem, but it is surprising and therefore causing concern. you should address with rigorous safety review asap. pfizer and moderna must get the plasmid out of future vaccines."
https://twitter.com/P_J_Buckhaults/status/1679294823612727297

More of his thoughts here:https://twitter.com/P_J_Buckhaults/status/1669732882934550528

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[redacted] The Epoch Times

[redacted]

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[redacted] The Epoch Times

[redacted]

--

[redacted] The Epoch Times

[redacted]

From: Maddison, Anna (HC/SC)
Sent: 2023-07-18 3:02 PM
To: [redacted]
Subject: RE: Questions for article on DNA plasmid contamination of COVID-19 vaccines

---

Hi again [redacted]

I just wanted to let you know that unfortunately we won't be able to get back to you with a response today.

If you are still interested in receiving a response after your deadline, I'll continue working on it and will do my best to get back to you as soon as I can.

Thanks,
Anna

From: [redacted]
Sent: Monday, July 17, 2023 12:39 PM
To: Maddison, Anna (HC/SC) <anna.maddison@hc-sc.gc.ca>
Subject: Re: Questions for article on DNA plasmid contamination of COVID-19 vaccines

[redacted] Thank you, Anna.

On Mon, Jul 17, 2023 at 12:38 PM Maddison, Anna (HC/SC) <anna.maddison@hc-sc.gc.ca> wrote:

> Hi [redacted] – confirming receipt of your request below.
>
> What is your deadline?
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> Thanks,
> Anna
>
> ---
> **Anna Maddison**
> She, her / elle
> Senior Media Relations Advisor | Communications and Public Affairs Branch
> Serving Health Canada and the Public Health Agency of Canada | Government of Canada
> anna.maddison@hc-sc.gc.ca | Mobile : 613-462-6617

Conseillère principale des relations avec les médias | Direction générale des affaires publiques et de communications
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anna.maddison@hc-sc.gc.ca | Mobile : 613-462-6617
- - -
Media | Média T: 613-957-2983 E/CE: media@hc-sc.gc.ca

From: [redacted]
Sent: Monday, July 17, 2023 10:21 AM
To: HEALTH MEDIA SANTÉ (HC/SC) <media@hc-sc.gc.ca>
Subject: Questions for article on DNA plasmid contamination of COVID-19 vaccines

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Categories: Dispatched

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[redacted]
The Epoch Times
[redacted]

From: [redacted]
Sent: 2023-08-16 12:27 PM
To: HEALTH MEDIA SANTÉ (HC/SC)
Subject: Genome modification

Categories: ack'd, Dispatched, New call for list

Good day,

Scientist Dr. Buckhaults said yesterday "i guarantee you there has been genome modification" in reference to his latest findings surrounding covid vax contamination.
https://twitter.com/P_J_Buckhaults/status/1691596093422006333

I know Health Canada's position on the matter, which you relayed to us in recent weeks. But you've also admitted having been unaware of the presence of SV40 in the vax, until McKernan and Buckhaults made the independent finding.

Have you tried to independently verify other findings made by the scientists?

Are you able to disprove Buckhaults' latest assertion, without relying on old assurances given by the manufacturer?

Are you currently assessing what would be the impact on the health of Canadians if Buckhaults is right about there being a genome modification?

Thank you and best regards,

[redacted]
The Epoch Times
195 Allstate Parkway
Markham, ON, L3R 1P8
P [redacted]
E [redacted]
www.TheEpochTimes.com